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PATENT APPLICATION

ATTORNEY DOCKET NO. 200315907-1

IN THE
UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Daniel R. Blakley

Confirmation No.: 6580

Application No.: 10/758,813

Examiner: R. Holmes

Filing Date: January 16, 2004

Group Art Unit: 3762

Title: SYNTHESIZING A REFERENCE VALUE IN AN ELECTROCARDIAL WAVEFORM

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TRANSMITTAL OF APPEAL BRIEF

Transmitted herewith is the Appeal Brief in this application with respect to the Notice of Appeal filed on May 10, 2007.

The fee for filing this Appeal Brief is (37 CFR 1.17(c)) $500.00.

(complete (a) or (b) as applicable)

The proceedings herein are for a patent application and the provisions of 37 CFR 1.136(a) apply.

☐ (a) Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)-(d)) for the total number of months checked below:

☐ 1st Month $120	☐ 2nd Month $450	☐ 3rd Month $1020	☐ 4th Month $1590

☐ The extension fee has already been filed in this application.

☒ (b) Applicant believes that no extension of time is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

Please charge to Deposit Account 08-2025 the sum of $ 500. At any time during the pendency of this application, please charge any fees required or credit any over payment to Deposit Account 08-2025 pursuant to 37 CFR 1.25. Additionally please charge any fees to Deposit Account 08-2025 under 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees. A duplicate copy of this sheet is enclosed.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of			Dated: July 10, 2007
DANIEL R. BLAKLEY			HP Docket No. 200315907-1
Serial No.	:	10/758,813	Examiner R. Holmes
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For	:	SYNTHESIZING A REFERENCE VALUE IN AN ELECTROCARDIAL WAVEFORM	

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Sir:

BRIEF OF APPELLANT

This Brief is presented in opposition to the Examiner's rejection of claims 1-32 in the final Office action dated February 27, 2007.

I. Real Party In Interest

The real party in interest is Hewlett-Packard Development Company, LP, a limited partnership established under the laws of the State of Texas and having a principal place of business at 20555 State Hwy 249, Houston, Texas 77070, U.S.A. (hereinafter "HPDC"). HPDC is a Texas limited partnership and is a wholly-owned affiliate of Hewlett-Packard Company, a Delaware Corporation, headquartered in Palo Alto, CA. The general or managing partner of HPDC is HPQ Holdings, LLC.

II. Related Appeals and Interferences

There are no known related appeals or interferences.

III. Status of Claims

The present application was filed on January 16, 2004 with original claims 1-32. In his response dated November 24, 2006, Appellant amended claims 1-10, 12-25 and 27-32. Claims 1-32, as amended in the response dated November 24, 2006, are the claims at issue in this appeal. Claims 1-32 stand rejected.

IV. Status of Amendments

No amendments have been made subsequent to the final Office action dated February 27, 2007.

V. Summary of Claimed Subject Matter

The summary is set forth in exemplary embodiments. Discussions of selected elements and recitations of claimed subject matter can be found at least at the cited locations in the specifications and drawings.

Independent claim 1 is directed to a method for applying a reference value to an electrocardial waveform as described in the flowchart of Fig. 7 and discussed at page 8, lines 5-33 and page 9, lines 1-21. The claimed method includes identifying a triggering event in an electrocardial waveform (200), waiting a period of time after the triggering event (230), sampling the waveform during an interval of relative inactivity (240) and dynamically referencing the waveform to the sample (250).

Independent claim 10 is directed to a system for generating a reference value for an electrocardial waveform as shown in Figs. 4 and 5, and discussed at page 4, lines

10-33 through page 8, lines 1-4. The claimed system includes an electrode input (45), an event detector (70) to detect an event in a waveform, a sampling device (85) that determines a reference value in the waveform, a timing device (80) that activates the sampling device after a period, and a referencing element (95) that applies the reference value to a voltage signal over a period.

Independent claim 16 is directed to a device for recording an electrocardial waveform as shown in Figs. 4 and 5, and discussed at page 4, lines 10-33 through page 8, lines 1-4. The claimed device includes at least one input (45) for receiving a signal representing an electrocardial waveform from an electrode, a sampling element (125), a memory element (130), a processor (140) configured to identify a peak value and determine a voltage value during an interval of inactivity, and a reference voltage generator (145) that generates a voltage applied to the incoming signal.

Independent claim 22 is directed to a receiver for receiving an electrocardial signal as shown in Figs. 4 and 5, and discussed at page 4, lines 10-33 through page 8, lines 1-4. The claimed receiver includes digital functionality including means for characterizing an electrocardial signal with a detector element (70) for identifying a feature, a sampling element (85) to determine a value of the signal, and timing means (80) to activate the sampling element. The claimed receiver further includes analog means coupled to the digital means (125) with a generator (145) configured to output a voltage and an integrating element (95) to apply the generated voltage to the electrocardial signal.

Independent claim 27 is directed to a computer readable media having instructions that, when executed, implement a method for synthesizing a reference value for an electrocardial waveform as discussed in the flowchart of Fig. 7 and described at page 8, lines 5-33 and page 9 lines 1-21. The claimed media method instructions include identifying a triggering event in an electrocardial waveform (200), sampling the waveform during an interval of inactivity (240), and referencing the waveform to the sample (250), where the triggering event includes a first and a second feature of the electrocardial waveform.

VI. Grounds of Rejection

In the Office action dated February 27, 2007, claims 1-15 and 27-32 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nearing et al. (U.S. Patent No. 6,169,919);

Claim 16-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nearing in view of Ekstrom (U.S. Patent No. 3,868,567).

VII. Argument

A. *Rejections under 35 U.S.C. §§ 102*

Claims 1-15 and 27-32 were rejected under 35 USC 102(b) as being anticipated by Nearing. Appellant respectfully disagrees that the Nearing reference discloses each and every element of the rejected claims.

In order to anticipate a claim under 35 U.S.C. § 102, a reference must teach each and every element as set forth in the claim. That is, the identical invention must be shown in as complete detail as is contained in the patent claim. *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (CAFC 1989).

Independent claim 1 recites:

> A method for applying a reference value to an electrocardial waveform including a series of heart beats, the method comprising:
> identifying a triggering event within the electrocardial waveform;
> waiting a period of time after the triggering event for an interval of relative inactivity in the waveform;
> sampling the electrocardial waveform during the interval of relative inactivity to provide a sample voltage value corresponding to a selected beat; and
> dynamically referencing the electrocardial waveform to the sample voltage value over a period of the selected beat.

Nearing states "...a spline curve is fit to the second, third and fourth isoelectric values [of second, third and fourth beats]...the values of the spline curve...are subtracted from the ECG data...." [Col. 6 ll. 2-6] Nearing does not disclose dynamic referencing of a voltage value over a period of a beat. Nearing "...subtracts values of the spline curve from the corresponding values of the ECG data..." at multiple points in a beat of the waveform. For at least the foregoing reasons, Appellant submits that claim 1 is allowable over Nearing.

Independent claim 10 uses language similar to claim 1 including: "a referencing element that applies the reference value to the voltage signal over a period of the selected beat." Again, Nearing does not disclose manipulation or referencing of any voltage signals. Nearing manipulates a digitized signal and "...subtracts values of the spline curve from the corresponding values of the ECG data..." at multiple points over a

beat. This is different than applying a reference voltage over a period of a beat. Nearing digitizes the signal as an initial process step and does not manipulate any analog signals after this initial step. Claim 10 specifically states the reference value is applied to a voltage signal. For at least the reasons set forth above, Appellant submits that claim 10 is allowable over Nearing.

Independent claim 27 includes "...wherein the **triggering event includes a first and a second feature** of the electrocardial waveform." The Examiner cites Nearing in rejecting claim 27, but does not identify specific language for the rejection. Nearing does not disclose the use of first and second features as triggering events. Nearing only uses the apex of the R-wave as a determining reference. Nearing states "...the location of the TP segment of each beat is determined based on the apex of the R-wave." [Col. 6 ll. 43-45] Appellant thus submits that Nearing does not anticipate or render obvious the subject matter of claim 27 and that claim 27 should be allowed.

As claims 2-9, 11-15 and 28-32 depend directly or indirectly from claims 1, 10 and 27, Appellant submits that such claims are not anticipated or rendered obvious by Nearing for at least the same reasons as set forth above with respect to claims 1, 10 and 27.

As discussed above, in the absence of a disclosure of each and every element of the rejected claims and in view of the teaching of the cited references, claims 1-15 and 27-32 are not anticipated under 35 U.S.C. § 102(b). Appellant therefore respectfully requests that the rejection of claims 1-15 and 27-32 be withdrawn.

B. Rejections under 35 U.S.C. §§ 103

Claims 16-26 were rejected under 35 USC 103(a) as being unpatentable over Nearing in view of Ekstrom, where Ekstrom discloses a method for measuring the difference in voltage levels of two isoelectric points in a recorded ECG waveform. Appellant respectfully disagrees that the Nearing reference and the Ekstrom reference, alone or together, disclose each and every element of the rejected claims, and suggest that Ekstrom in view of Nearing fails to establish a *prima face* case of obviousness. When the claims are reviewed under the current standards for obviousness as set by the Federal Circuit Court of Appeals and the Board of Patent Appeals and Interferences, the impropriety of the rejections becomes clear.

1. STANDARD OF REVIEW

Obviousness is a question of law based on (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). "In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). "If examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

The Manual of Patent Examining Procedure sets forth three basic criteria that must be met to establish a *prima facie* case of obviousness (MPEP § 2143):

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.
>
> The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991))

The law is "clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (citations omitted).

2. ***THE CITED REFERENCES COMBINED DO NOT TEACH OR SUGGEST EVERY ELEMENT OF THE CLAIMS***

Independent claim 16 recites:

> A device for recording an electrocardial waveform, comprising:
> at least one input for receiving a signal from an electrode, the signal representing an electrocardial waveform;
> a sampling element to digitize the received signal;
> a memory element coupled to the at least one input, that stores the digitized signal;
> a processor, coupled to the memory, and configured to:
> identify a peak value of the received signal; and
> determine a voltage value of the received signal during an interval of relative inactivity, the interval located relative to the peak value; and
> a reference voltage generator for generating a voltage applied to the incoming signal substantially equal to the determined voltage value.

Independent claim 16 recites a reference voltage generator. Independent claim 16 also recites applying a voltage to an electrocardial signal. Neither Nearing nor Ekstrom (nor any combination thereof) disclose analog components for generating a voltage. Neither Nearing nor Ekstrom (nor any combination thereof) disclose applying a voltage to an incoming signal.

Claim 22 recites:

> A receiver for an electrocardial signal, comprising:
> digital means for characterizing an electrocardial signal, the digital means including:
> a detector element for identifying at least one distinct feature of the signal;
> a sampling element to determine a value for an interval of the signal; and
> timing means to activate the sampling element after the feature is detected and at the start of the sampled interval; and
> analog means operably coupled to the digital means for modifying the electrocardial signal, the analog means including;
> a generator configured to output a voltage signal level as a function of the interval value; and

an integrating element to integrate the electrocardial signal with the generator signal.

Independent claim 22 thus expressly recites analog components for outputting a voltage signal level as a function of the interval value, and for integrating the electrocardial signal with the generator signal. Both Nearing and Ekstrom manipulate digital ECG signals and not analog ECG voltage signals. Ekstrom digitizes the ECG signal "as a binary bit stream" as an initial step [Col 5 ll. 3]. Nearing states that "in a first step a digitized signal is received for processing." [Col 4 ll. 39-40] Neither Ekstrom nor Nearing reference an analog ECG waveform after these initial digitizing steps. Claim 22 thus is distinguishable from both Nearing and Ekstrom, and any combination thereof, and should be allowed.

3. NO TEACHING, SUGGESTION, OR MOTIVATION TO COMBINE THE CITED REFERENCES

The Examiner has failed to provide a sufficient suggestion or motivation in the prior art to combine or modify the reference teachings so as to arrive at the claimed invention. While both Nearing and Ekstrom analyze signal characteristics, they use different digitizing techniques; different analysis hardware and they have diverging objectives.

Ekstrom and Nearing use distinct and incompatible digitizing techniques requiring distinctly different hardware, and there is no motivation to combine the references. Ekstrom utilizes binary logic devices including flip flop circuits and bilateral switches in analyzing a binary bit stream representation of the ECG signal to determine a delta value. Nearing is converting the ECG signal to integer values and analyzing and comparing alternating waveforms with software algorithms. The circuit components of

Ekstrom are configured to operate on a binary bit stream and will not function with the integer base digitization used by Nearing.

The dissimilarity of the references is illustrated by the figures in the Nearing and Ekstrom patents. Ekstrom discloses an array of circuit components in five figures of circuits, and the balance of the figures disclose binary signal diagrams. Nearing discloses no circuit components in the figures or in the disclosure. Nearing and Ekstrom operate on different data formats requiring different circuit components which are not compatible. There is no motivation to combine these two references, and if combined, there is little likelihood for success.

The objectives of Nearing and Ekstrom also are distinct and divergent. Nearing discloses a method for "...calculating a magnitude of alteration in the T-waves of an electrocardiogram signal...as a marker of electrical instability..." [Col.1, lines 20-27] and "... [t]he ECG data are used to calculate an odd median complex for the odd beats in the ECG data and an even median complex for the even beats in the ECG data." [Col. II. 53-55] Nearing measures specific waveform characteristics and compares the characteristics in alternating waveforms, developing a median complex for an even set of beats and a separate median complex for an odd set of beats in an ECG digitized signal. Ekstrom "yields an averaged depression of the ST segment of an ECG relative to the PQ segment of the same ECG." Ekstrom is comparing the magnitude of two isoelectric points within a single beat of the waveform in a bit stream representation of the ECG signal. In summary, Ekstrom uses bit processing components to derive a difference value between two isoelectric points within a beat. Nearing uses software

algorithms to develop complexes for an even series of beats and an odd series of beats. The objectives of Ekstrom and Nearing are clearly distinct and divergent. Digitizing techniques and analysis hardware used by each show there is no motivation to combine these references, and if they were combined there would be no expectation of success.

In view of the arguments presented above, Appellant submits that independent claims 16 and 22 are neither anticipated nor rendered obvious by the cited references. Appellant respectfully requests the withdrawal of the rejection of claims 16 and 22 under 35 U.S.C. § 103(a). Claims 17-21 and 23-26 depend directly or indirectly from claims 16 and 22, and thus are similarly not anticipated or rendered obvious by Nearing in view of Ekstrom (either individually or in combination) for at least the reasons set forth above with respect to claims 16 and 22.

In the absence of a disclosure of each and every element of the rejected claims in the cited reference, or the identification of an appropriate suggestion or motivation to modify the teachings of the reference so as to arrive at the claimed invention, Appellant submits that the Examiner has failed to establish the *prima facie* obviousness of claims 16-26.

C. CONCLUSION

As discussed above, in the absence of a disclosure of each and every element of the rejected claims, the absence of specific motivation or suggestion in the cited reference to combine or modify the reference teachings as suggested by the Examiner, and in view of the teaching of the cited references, it Is submitted that claims 1-32 are neither anticipated under 35 U.S.C. § 102(b) nor rendered obvious under 35 U.S.C. §

103. Appellant therefore respectfully requests the withdrawal of the rejection of those claims.

VIII. CLAIMS APPENDIX

1. A method for applying a reference value to an electrocardial waveform including a series of heart beats, the method comprising:

identifying a triggering event within the electrocardial waveform;

waiting a period of time after the triggering event for an interval of relative inactivity in the waveform;

sampling the electrocardial waveform during the interval of relative inactivity to provide a sample voltage value corresponding to a selected beat; and

dynamically referencing the electrocardial waveform to the sample voltage value over a period of the selected beat.

2. The method of claim 1, wherein the interval of relative inactivity occurs during a TP interval of the electrocardial waveform.

3. The method of claim 1, wherein the triggering event is a peak R-value in a QRS complex of the electrocardial waveform.

4. The method of claim 1, wherein the triggering event is a peak R-value in a QRS complex of the electrocardial waveform followed by at least one of a negative S peak in the QRS complex and a T wave.

5. The method of claim 1, wherein the triggering event is a peak R-value in a QRS complex followed by a period of at least 0.2 seconds of relative inactivity.

6. The method of claim 1, further comprising measuring a value of the interval of relative inactivity between successive peak R values and modifying the length of the period of time waiting in response to the measured interval values.

7. The method of claim 1, wherein the sample voltage value supplants a ground provided by a reference electrode used in recording the electrocardial waveform.

8. The method of claim 1, wherein referencing the electrocardial waveform includes supplying a reference voltage substantially equal to the value of the sampled waveform during the interval of relative inactivity.

9. The method of claim 1, wherein identifying the triggering event additionally comprises detecting frequency components in the electrocardial waveform.

10. A system for generating a reference value for an electrocardial waveform including a series of beats, comprising:

at least one electrode input that conveys a voltage signal of the electrocardial waveform of a patient;

an event detector that detects an event within the electrocardial waveform;

a sampling device that determines the reference value corresponding to a selected beat;

a timing device that, after a wait period in response to the event detector, activates the sampling device; and

a referencing element that applies the reference value to the voltage signal over a period of the selected beat.

11. The system of claim 10, wherein the reference value is substantially zero volts.

12. The system of claim 10, wherein the event is an R peak of a QRS complex of the electrocardial waveform.

13. The system of claim 10, wherein the event is an interval of relative inactivity followed by a peak of a QRS complex of the electrocardial waveform.

14. The system of claim 10, wherein the sampling device measures a rate of change in the voltage signal of the electrocardial waveform, and determines the reference value based at least in part on the rate of change in the voltage signal.

15. The system of claim 10, further comprising a processor, coupled to the timing device, configured to measure the time between successive corresponding events in the electrocardial waveform and to modify a length of the wait period in response to the measured time.

16. A device for recording an electrocardial waveform, comprising:

at least one input for receiving a signal from an electrode, the signal representing an electrocardial waveform;

a sampling element to digitize the received signal;

a memory element coupled to the at least one input, that stores the digitized signal;

a processor, coupled to the memory, and configured to:

identify a peak value of the received signal; and

determine a voltage value of the received signal during an interval of relative inactivity, the interval located relative to the peak value; and

a reference voltage generator for generating a voltage applied to the incoming signal substantially equal to the determined voltage value.

17. The device of claim 16, further comprising an amplifier that subtracts the generated voltage from the at least one received signal.

18. The device of claim 16, wherein the identified peak value is an R peak of a QRS portion of the electrocardial waveform.

19. The device of claim 16, wherein the interval of relative inactivity occurs after a T wave of a first sinus rhythm event but prior to a P wave of a second sinus rhythm event, wherein both sinus rhythm events are components of the electrocardial waveform.

20. The device of claim 16, wherein the processor adjusts the interval sampled as a function of the time between the peak value of a first sinus rhythm event and the peak value of a second sinus rhythm event, wherein both sinus rhythm events are components of the electrocardial waveform.

21. The device of claim 16, wherein the processor additionally detects frequency components in the received signal.

22. A receiver for an electrocardial signal, comprising:

digital means for characterizing an electrocardial signal, the digital means including:

a detector element for identifying at least one distinct feature of the signal;

a sampling element to determine a value for an interval of the signal; and

timing means to activate the sampling element after the feature is detected and at the start of the sampled interval; and

analog means operably coupled to the digital means for modifying the electrocardial signal, the analog means including;

a generator configured to output a voltage signal level as a function of the interval value; and

an integrating element to integrate the electrocardial signal with the generator signal.

23. The receiver of claim 22, wherein the at least one distinct signal feature includes an R peak of a QRS complex of the electrocardial signal.

24. The receiver of claim 23, wherein the at least one distinct signal feature includes a negative peak of the QRS complex.

25. The receiver of claim 22, wherein the at least one distinct signal feature includes an interval of relative inactivity followed by an R peak of a QRS complex.

26. The receiver of claim 22, additionally comprising means for detecting frequency components in the electrocardial signal.

27. A computer-readable media having computer-readable instructions thereon, which, when executed by a computer, cause the computer to execute a method for synthesizing a reference value for an electrocardial waveform, the method comprising:

identifying a triggering event within the electrocardial waveform;

sampling the electrocardial waveform during an interval of relative inactivity; and

referencing the electrocardial waveform to the sample;

wherein the triggering event includes a first and a second feature of the electrocardial waveform.

28. The method for synthesizing a reference value of claim 27, further comprising waiting a period of time after identifying the triggering event until the electrocardial waveform enters a TP interval.

29. The method for synthesizing a reference value of claim 27, wherein the interval of relative inactivity occurs during a TP interval of the electrocardial waveform.

30. The method for synthesizing a reference value of claim 27, wherein sampling the waveform provides a sample voltage value corresponding to a selected beat, and wherein referencing the waveform to the sample includes dynamic referencing of the sampled voltage value over a period of the selected beat.

31. The method for synthesizing a reference value of claim 27, wherein the triggering event is a peak R value in a QRS complex of the electrocardial waveform followed by at least one of a negative peak in the QRS complex and a T wave.

32. The method for synthesizing a reference value of claim 27, wherein referencing the waveform includes supplying a reference voltage substantially equal to a sample voltage value.

IX. Evidence Appendix

None.

X. Related Proceedings Appendix

None.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to Examiner R. Holmes, Group Art Unit 3762, Assistant Commissioner for Patents, at facsimile number (571) 273-8300 on July 10, 2007.

Heidi Dutro